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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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Sheet

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of

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**Complete if Known**

Application Number	10/528,577
Filing Date	March 21, 2005
First Named Inventor	Ulrich Speck et al.
Art Unit	March 21, 2005
Examiner Name	Laura A. Bouchelle
Attorney Docket Number	WEICKM-0044

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
A1	4 776 337	10-11-1988	PALMAZ ET AL.		
A2	4 217 894	08-19-1990	FRANETZKI ET AL.		
A3	4 997 643	03-05-1991	PARTAIN ET AL.		
A4	5 306 266	10-22-1991	STACK ET AL.		
A5	5 102 402	04-07-1992	DROR ET AL.		
A6	5 789 018	08-04-1992	ENGELSON ET AL.		
A7	5 157 049	10-20-1992	RUDIGER ET AL.		
A8	5 176 626	01-05-1993	SOEHENDRA ET AL.		
A9	5 234 456	08-10-1993	SILVESTRIN, THOMAS A		
A10	5 629 881	05-13-1997	LEEB ET AL.		
A11	5 960 972	11-06-1999	DING ET AL.		
A12	6 013 092	01-11-2000	DEHDASHTIAN ET AL.		
A13	6 071 285	06-06-2000	LASHINSKI ET AL.		
A14	2001 0037140	11-01-2001	GAUDOIN ET AL.		
A15	2002 0098278	07-25-2002	BATES ET AL.		
A16	2003 007944	01-09-2003	O'HALLORAN ET AL.		
A17	2004 115228	06-17-2004	COSTA ET AL.		
A18	7 445 792	09-18-2004	TONER ET AL.		
A19	2004 0224003	11-11-2004	SCHULTZ ET AL.		
A20	2005 063926	03-24-2005	BATHINA ET AL.		
A21	2008 0102033	05-01-2008	SPECK ET AL.		
A22	2008 0118544	05-22-2008	WANG LIXIAO		
A23	2008 0175687	07-24-2008	WANG LIXIAO		
A24	2008 0255508	10-16-2008	WANG LIXIAO		
A25	2008 0255509	10-16-2008	WANG LIXIAO		
A26	2008 0255510	10-16-2008	WANG LIXIAO		
A27	6 682 545	01-27-2004	KESTER ET AL.		
A28	5 814 301	09-29-1998	KLOPP ET AL.		
A29	2008 010234	05-01-2008	SPECK ET AL.		

**FOREIGN PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	* <sup>2</sup>
B1		JP-06-063145	03-08-1994	KUAAYU KK		C57
B2		JP-07-328124	12-19-1995	TERUMO CORP.		C58
B3		DE-20122736	08-09-2007	BAYER SCHERING PHARMA AG		A29
B4		WO-03/41686	05-22-2003	MEDLOGIC GLOBAL LTD.		
B5		JP-20000507930	06-27-2000			B82
B5		JP-10509691	09-22-1998			B81

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Application Number	10/528,577
Filing Date	March 21, 2005
First Named Inventor	Ulrich Speck et al.
Art Unit	March 21, 2005
Examiner Name	Laura A. Bouchelle
Attorney Docket Number	WEICKM-0044

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B7		JP-7500585	01-19-1995			A28
B8		EP-0357003	03-07-1990	CORVITA CORP.		
B9		WO-90/13293	11-15-1990	UNIV SYRACUSE		
B10		WO-90/13332	11-15-1990	CEDARS SINAI MEDICAL CENTER		
B11		WO-91/12779	09-05-1991	MEDTRONIC, INC		
B12		WO-91/12779	09-05-1991	MEDTRONIC		
B13		EP-0470246	02-12-1992	MEDTRONIC, INC.		B12
B14		WO-92/11896	07-23-1992	BOSTON SCIENTIFIC CORP.		
B15		WO-92/12717	08-06-1992	BREM ET AL.		
B16		WO-93/06792	04-05-1993	SCIMED LIFE SYSTEMS, INC.		
B17		WO-93/09765	05-27-1993	AMSDEN ET AL.		
B18		WO-93/09762	05-27-1993	LONG ET AL.		
B19		WO-93/11120	06-10-1993	ZYNAxis TECH., INC.		
B20		WO-93/11668	06-24-1993	RUSH PRESBYTERIAN ST. LUKE		
B21		EP-0578998	01-19-1994	STRECKER ERNST		A4
B22		JP-06-63145	03-08-1994	BUAYU KK		C57
B23		WO-94/07529	04-14-1994	NEORX CORP.		
B24		EP-0604022	06-29-1994	ADVANCED CARDIOVASCULAR SYSTEMS		
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B26		EP-0623354	11-09-1994	MEDTRONIC, INC.		
B27		WO-94/25020	11-10-1994	PHARMACIA AB		
B28		WO-94/26291	11-24-1994	NEORX CORP.		
B29		DE-4334272	04-13-1995	STEMBERGER, AXEL, DR.		A82
B30		EP-673114	09-20-1995	SIEMENS AG		A10
B31		EP-0681475	11-15-1995	NEORX CORP.		B25
B32		JP-7-328124	12-19-1995	TERUMO CORP.		C58

Examiner Signature

Date Considered

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First Named Inventor	Ulrich Speck et al.
Art Unit	March 21, 2005
Examiner Name	Laura A. Bouchelle
Attorney Docket Number	WEICKM-0044

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>2</sup> – Number <sup>3</sup> – Kind Code <sup>4</sup> (# known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
B34		EP-0717041	06-19-1996	SQUIBB BRISTOL MYERS CO.		
B36		EP-0747069	12-11-1996	COOK, INC.		
B37		WO-97/01327	01-06-1997	MACROCHEM CORP.		
B38		DE-69119753	01-23-1997	MEDTRONIC, INC.		A5
B39		WO-97/31674	09-04-1997	BOSTON SCIENTIFIC CORP.		
B40		EP-0797988	10-01-1997	ANGIOTECH, INC.		
B41		WO-97/41916	11-23-1997	EMED CORP.		
B42		WO-98/43618	10-08-1998	NEORX CORP.		
B43		WO-99/09729	02-25-1999	MAXON SYSTEM, INC		
B44		WO-99/08729	02-25-1999	BOSTON SCIENTIFIC CORP.		
B45		WO-99/30684	06-24-1999	SUPERGEN, INC.		
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B47		WO-00/00238	01-06-2000	QUANUM MEDICAL CORP.		
B48		WO-00/00023	01-06-2000	HYDROMER, INC.		
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B50		WO-00/47197	08-17-2000	QUANUM MEDICAL CORP.		
B51		EP-1037605	09-27-2000	SUPERGEN, INC.		B45
B52		EP-1090637	04-11-2001	ANGIOTECH, INC.		
B53		WO-01/24866	04-12-2001	PENN ST RES. FOUNDATION		
B54		WO-01/054748	08-02-2001	EDWARDS LIFESCIENCE CORP.		
B55		EP-1159974	12-05-2001	ANGIOTECH PHARMA, INC.		

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Art Unit	March 21, 2005
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B56		EP-1250166	10-23-2002	EDWARDS LIFE SCIENCE CORP.		B54
B57		WO04/006976	01-22-2004	COOK, INC.		
B58		WO-2004/022124	03-18-2004	ABBOTT LAB.		
B59		EP-1407786	04-14-2004	SCIMED LIFE SYSTEMS		
B60		EP-1447098	08-08-2004	BOSTON SCIENTIFIC LTD.		
B61		EP-1512398	03-09-2005	BOSTON SCIENTIFIC CORP.		
B62		EP-1521603	04-13-2005	COOK, INC.		B57
B63		EP-1536850	06-08-2005	ABBOTT LAB		B58
B64		WO-2005/089855	09-29-2005	ABBOTT LAB.		
B65		WO-2006/023104	03-02-2006	BOSTON SCIENTIFIC CORP.		
B66		EP-1666070	06-07-2006	ULRICH ET AL.		A21
B67		EP-1669091	06-14-2006	BOSTON SCIENTIFIC CORP.		
B68		EP-1695697	08-30-2006	ANGIOTECH, INC.		
B69		EP-1695698	08-30-2006	ANGIOTECH, INC.		
B70		EP-1735042	12-27-2006	ABBOTT LAB		B64
B71		EP-1781209	05-09-2007	BOSTON SCIENTIFIC LTD., SCIMED, INC.		B65
B72		WO-08/063576	05-29-2008	LUTONIX, INC.		
B73		WO-09/051615	04-23-2009	LUTONIX, INC.		
B74		WO-09/051614	04-23-2009	LUTONIX, INC.		
B75		WO-09/051616	04-23-2009	LUTONIX, INC.		
B76		WO-09/051618	04-23-2009	WANG LIXIAO		
B77		EP-2092941	08-26-2009	LUTONIX, INC.		
B78		EP-2092942	08-26-2009	LUTONIX, INC.		
B79		EP-2098230	09-09-2009	BOSTON SCIENTIFIC LTD., SCIMED, INC.		
B80		CA-2 207 025	06-13-1996	WERNER ET AL.		
B81		WO-97/33552	09-18-1997	WALLACE TECH, INC.		
B82		CA-2 218 103	10-17-1996	BEHRINGWER KE AG		

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Sheet 5 of 9

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<i>Filing Date</i>	March 21, 2005
<i>First Named Inventor</i>	Ulrich Speck et al.
<i>Art Unit</i>	March 21, 2005
<i>Examiner Name</i>	Laura A. Bouchelle
<i>Attorney Docket Number</i>	WEICKM-0044

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	C1	Japanese Final Rejection in Co-pending Application No. JP2004-538994 dated March 9, 2010.	
	C2	Opposition to corresponding EP1539266 by Boston Scientific Ltd., March 10, 2010.	
	C3	LIGGINS, RICHARD T. ET AL., "Paclitaxel loaded poly(L-lactic acid) microspheres: properties of microspheres made with low molecular weight polymers." International Journal of Pharmaceutics, 2001, Vol. 222, pp. 19-33	
	C4	DORDUNCOO, S. K. ET AL., "Release of taxol from poly( $\epsilon$ -caprolactone) pastes: effect of water-soluble additives." Journal of Controlled Release, 1997, Vol. 44, pp. 87-94	
	C5	WICHERT, B ET AL., "Low Molecular weight PLA: a suitable polymer for pulmonary administered microparticles?" J. Microencapsulation, 1993, Vol. 10, No. 2, pp. 195-207	
	C6	NAIRN, JOHN A., "Polymer Characterization." Materials Science & Engineering 5473, 2003, Ch. 3, pp. 43-55	
	C7	LAMBA, NINA M. K. ET AL., "Structure and Physical Characterization of Polyurethanes,"Polyurethanes in Biomedical Applications. Ch. 4, pp. 43-52	
	C8	CREMERS ET AL., "V1742 – Paclitaxel-beschichtete PTCA-Katheter: Gibt es Unterschiede? Einfluss von PACCOCATH und DIOR Ballonkathereter auf die Neointimalproliferation an Schweinekoronarien." Clin. Res. Cardiol., 1997	
	C9	CREMERS, B ET AL., "Comparison of two different paclitaxel-coated balloon catheters in the porcine coronary restenosis model." Clin. Res. Cardiol., 2009, Vol. 98, pp. 325-330	
	C10	GROSSMANN, S. "Neuartige Zubereitungen Hemmung der Neointimalproliferation in verengten Arterien," Dissertation zur Erlangung des akademischen Grades des Doktors der Naturwissenschaften (Dr. rer. nat.), November 2006	
	C11	SOLLOTT, STEVEN J. ET AL., "Taxol Inhibits Neointimal Smooth Muscle Cell accumulation after angioplasty in the rat." The Journal of clinical Investigation, April 1995, Vol. 95, pp. 1869-1876	
	C12	BC, "Lippold in Retardarneiformen" in E. Nurnberg, Hagers Handbuch der pharmazeutischen Praxis, Vol. 2, Springer-Verlag Berlin Heidelberg New York, 5 <sup>th</sup> edition, 1991, pp. 832-840	
	C13	LANGER, R., "New methods of drug delivery." Science, September 28, 1990, Vol. 249, pp. 1527-1533	

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## NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	C14	KIRK-OTHMER, ENCYCLOPEDIA OF CHEMICAL TECHNOLOGY, 3 <sup>rd</sup> Edition, Vol. 17, 1982, John Wiley & Sons, pp. 281-310	
	C15	VOIGT, R., Lehrbuch der pharmazeutischen Technologie, 5 <sup>th</sup> edition, VEB Verlag Volk und Gesundheit Berlin, 1984, p. 689	
	C16	TAWASHI, R. "The dissolution rates of crystalline drugs." J. Mond. Pharm. 1968, Vol. 4, No. 11, pp. 371-379	
	C17	U. S. 08/094,536 (Priority of D2)	
	C18	Coomber and Gottlieb, Arteriosclerosis, 1990, Vol. 10, No. 2, pp. 215-222	
	C19	BARTOLI ET AL., J. Microencapsulation, 1990, Vol. 7, No. 2, pp. 191-197	
	C20	KATSUDA ET AL., Clin. Ter. Cardiovasc. IX(4), pp. 245-248	
	C21	GARCIA-MATINEZ ET AL., "Effects of taxol on endothelial cells of the developing semilunar heart valves in the chick embryo." Acta Anat. 1988, Vol. 133, pp. 282-288	
	C22	Package Insert for Taxol	
	C23	MULLER ET AL., JACC, 1990, Vol. 17, No. 6, pp. 126B-131B	
	C24	SLEPIAN, in textbook of interventional cardiology, 1990, Section IV, Chapter 32, pp. 647-670	

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet | 7 | of | 9

<i><b>Complete if Known</b></i>	
Application Number	10/528,577
Filing Date	March 21, 2005
First Named Inventor	Ulrich Speck et al.
Art Unit	March 21, 2005
Examiner Name	Laura A. Bouchelle
Attorney Docket Number	WEICKM-0044

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	C25	DICHEK ET AL., "Seeding of Intravascular stents with genetically engineered endothelial cells," Circulation, Vol. 80, No. 5, pp.1347-1353	
	C26	Single e-mail from SiGMA Chemical Company of February 15, 2007 to Dr. Sollot confirming that from 1991 – 1993 the material was listed in their catalog as "Taxol," and that the name was changed in their catalog from "taxol" to "paclitaxel" in 1994	
	C27	UK Court of Appeal Decision	
	C28	HIATT ET AL., "Drug-eluting stents for the prevention of restenosis: in quest for the Holy Grail," Catheterization and Cardiovascular Interventions, 2002, Vol. 55, pp. 409-417	
	C29	FORTH, W. ET AL. "Allgemeine und spezielle Pharmakologie und Toxikologie," 7 Auflage, Heidelberg: Spektrum Akademischer Verlag, 1996, Chapter, 1, 2, 3.	
	C30	LIGGINS, R. T. ET AL., J. Pharma. Sci., 1997, Vol. 86, pp. 1458-1463	
	C31	MATTHEW, R. T. ET AL., J. Med. Chem., 1992, Vol. 35, pp. 141-151	
	C32	TARR, B. D. et al., "J. Parent Sci. Technol., 1987, Vol. 41, pp. 31-33	
	C33	SWINDELL, C.S. ET AL., J. Med. Chem., 1991, Vol. 34, pp. 1176-1184	
	C34	SHARMA, U. S. ET AL., J. Pharma. Sci., 1995, Vol. 84, pp. 1223-1230	
	C35	U.S. Patent Application 08/062,451 (Priority of D3)	

Examiner Signature	Date Considered
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	C36	FDA ONCOLOGY TOOLS APPROVAL SUMMARY FOR PACLITAXEL	
	C37	FDA ONCOLOGY TOOLS PRODUCT LABEL DETAILS IN CONVENTIONAL ORDER FOR PACLITAXEL	
	C38	Technical Leaflet Cremphor EL	
	C39	BARATH ET AL., JACC, 1989, Vol. 13, No 4, pp. 252A	
	C40	COX ET AL., Coronary Artery Disease, 1992, Vol. 3, pp. 237-248	
	C41	VOISARD ET AL., Coronary Artery Disease, 1993, Vol. 4, pp. 935-942	
	C42	Untersuchungen in vitro and in vivo, Zeitschrift fur kardiologie, Band 89, Heft 5, 2000, pp. 390-397	
	C43	Printout from the website of Bayer HealthCare Pharmaceuticals, indicating that Ultravist has been commercially available since 1985	
	C44	Report demonstrating in the C6-ceramide is a lipophilic substance as defined by the patent in suit	
	C45	MITCHEL ET AL., Circulation, October 1994, Vol. 90, pp. 1979-1988	
	C46	KANDARPA ET AL., J. Vasc. Inter. Radiol., November/ December 1997, Vol. 8, pp. 997-1004	
	C47	KANDARPA ET AL., J. Vasc. Inter. Radiol., May/ June 1998, vol. 9, pp. 487-493	
	C48	BARON ET AL., "Cardiovascular Research, June 2000, Vol. 46, pp. 585-594	

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	C49	Office Action issued by the European Patent Office on September 15, 2005	
	C50	Claims enclosed with Office Action issued by European Patent Office on September 15, 2005	
	C51	Response filed on January 13, 2006	
	C52	Product Information on the DIOR balloon catheter from Eurocor GmbH	
	C53	Copy of the decision to revoke EP1140273 B1 (=D11EP) of October 23, 2007	
	C54	Clinical Cardiology Divergent Effects on Coronary Artery Disease: Abstract from 70 <sup>th</sup> Scientific Session: Circulation, Vol. 96, no. 8, October 21, 2007	
	C55	Definition of "partition coefficient" Wikipedia	
	C56	KHAN, I ET AL., Drug Development and Industrial Pharmacy, 2005, Vol. 31, pp. 59-78	
	C57	BUAAYK KK, "Balloon Catheter for Intravascular Dosing," Patent Abstracts of Japan, Publication Date: March 8, 1994, English Abstract of JP05-063145	
	C58	TERUMO CORP, "Medicine dosing catheter," Patent Abstracts of Japan, Publication Date: December 19, 1995, English Abstract of JP07-325124	

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